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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 08831-012	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/CA2005/000217	International filing date *(day/month/year)* 18 February 2005 (18-02-2005)	Priority date *(day/month/year)* 18 February 2004 (18-02-2004)

International Patent Classification (IPC) or national classification and IPC
IPC: ***A61B 5/0488*** (2006.01) , ***A61B 5/08*** (2006.01) , ***A61M 16/00*** (2006.01)

Applicant
MAQUET CRITICAL CARE AB ET AL

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of 6 sheets, as follows:
      [X] sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. 1 and the Supplemental Box.
   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))
      , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - [X] Box No. I Basis of the report
   - [ ] Box No. II Priority
   - [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - [ ] Box No. IV Lack of unity of invention
   - [X] Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - [ ] Box No. VI Certain documents cited
   - [ ] Box No. VII Certain defects in the international application
   - [ ] Box No. VIII Certain observations on the international application

Date of submission of the demand 19 December 2005 (19-12-2005)	Date of completion of this report 24 July 2006 (24-07-2006)
Name and mailing address of the IPEA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001(819)953-2476	Authorized officer Carl Ebsen (819) 997-2313

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CA2005/000217

Box No. I Basis of the report

1. With regard to the **language,** this report is based on:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into , which is the language of a translation furnished for the purposes of:

[ ] international search (Rules 12.3(a) and 23.1(b))

[ ] publication of the international application (Rule 12.4(a))

[ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

[ ] the international application as originally filed/furnished

[X] the description:

[X] pages 1-39 as originally filed/furnished

[ ] pages* received by this Authority on

[ ] pages* received by this Authority on

[X] the claims:

[ ] pages as originally filed/furnished

[ ] pages* as amended (together with any statement) under Article 19

[X] pages* 40 - 45 received by this Authority on 19 December 2005 (19.12.2005)

[ ] pages* received by this Authority on

[X] the drawings:

[X] pages 1-7 as originally filed/furnished

[ ] pages* received by this Authority on

[ ] pages* received by this Authority on

[ ] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/figs

[ ] the sequence listing *(specify):*

[ ] any table(s) related to sequence listing *(specify):*

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/figs

[ ] the sequence listing *(specify):*

[ ] any table(s) related to sequence listing *(specify):*

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-18	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-18	NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims	NONE	NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1: EP 1366779 A1, "Proportional pressure assist ventilation controlled by diaphragm electromyographic signal", 03 December 2003, Beck et al.

D2: WO 02056818 A2, "Myoelectrical activated respiratory leak sealing", 25 July 2002, Sinderby et al.

1.0 Novelty

Subject matter of claims 1-18 is deemed to fulfill the requirements of PCT Article 33(2).

2.0 Inventive Step

Claims 1-18 do not fulfill the requirements of inventive step under PCT Article 33(3).

D1 discloses a closed loop system which uses the intensity of a diaphragm electromyogram (EMG) for a given inspiratory volume, the inspiratory volume for a given EMG intensity, or a combination of the above, in view of controlling the level of gas flow, gas volume or gas pressure delivered by a mechanical (lung) ventilator. The closed loop ventilator system enables for automatic or manual adjustment of the level of inspiratory support in proportion to changes in the neuro-ventilatory efficiency such that the neural drive remains stable at a desired target level. An alarm can also be used to detect changes in neuro-ventilatory efficiency in view of performing manual adjustments.

D2 discloses a method and system for sealing/unsealing (regulating) airway leaks occuring between the ventilator circuit and respiratory airways during lung ventilatory support in response to myoelectrical activity of diaphgram. Myoelectrical activity of a patient's respiratory-related muscle is sensed to detect respiratory effort, and to produce a myoelectrical signal representative of the sensed muscle myoelectrical activity. Respiratory flow and pressure can also be measured to produce respective respiratory pressure and respiratory flow signals. A logic triggers sealing/unsealing of airway leaks in relation to the myoelectrical signal, respiratory flow signal and/or respiratory pressure signal to assist respiration of the patient. The amplitude of the myoelectrical signal is compared to a given threshold, and airway leaks are sealed when the amplitude of the myoelectrical signal is higher than this threshold. Increment of myoelectrical signal amplitude can also be detected to trigger the airway leak regulating device to seal the airway leaks, while decrement of the myoelectrical signal amplitude can be detected to unseal the airway leaks and thus permit air evacuation from the patient's lungs.

...continued in the supplemental box.

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of: V

In response to the applicant's letter dated June 15, 2006 the applicant argues that there is no neural deactivation of inspiratory muscles. In the abstract of D1 it states that "The closed loop ventilator system enables for automatic or manual adjustment of the level of inspiratory support in proportion to changes in the neuro-ventilatory efficiency.....An alarm can also be used to detect changes in neuro-ventilatory efficiency in view of performing manual adjustments." The inspiratory support which is directly related to inspiratory muscle function, is adjusted by neural means and it would not involve an inventive step to include "neural deactivation" as one of the adjustment capabilities. Neural deactivation of inspiratory muscles can also be seen on page 2, line 26 of D2.

Applicant argues that the threshold in D1 and D2 is not a calculated threshold. This seems to be the applicant's main argument. Simply having a calculated threshold is not a difference that would be considered to be inventive. Airway leaks in D2 are sealed when the amplitude of the myoelectrical signal is higher than the given threshold. The control of airway flow and/or pressure to prevent muscle fatigue can be seen in D1 and D2 combined. The given threshold in the prior art is pre-calculated based on respiratory flow and pressure. The applicant's claims as they presently stand are broad and do not overcome the prior art.

3.0 Industrial Applicability

Claims 1-18 fulfill the requirements of Industrial Applicability under PCT Article 33(4).

WHAT IS CLAIMED IS:

1. A method for determining a level of ventilatory assist to a ventilator-dependent patient for reducing the risk of respiratory muscle fatique, the method comprising:

calculating a respiratory muscle fatigue critical threshold of a respiration-related feature, wherein fatigue of a respiratory muscle of the ventilator-dependent patient develops when the critical threshold is reached by the respiration-related feature; and

controlling the level of ventilatory assist to the ventilator-dependent patient in relation to the critical threshold of the respiration-related feature so as to prevent fatigue of the patient's respiratory muscle.

2. A method for determining a level of ventilatory assist as defined in claim 1, wherein:

calculating a critical threshold of the respiration-related feature comprises calculating a critical signal strength of an electrical activity of the patient's respiratory muscle above which muscle fatigue develops; and

controlling the level of ventilatory assist comprises preventing the signal strength of the electrical activity of the patient's respiratory muscle to exceed the critical signal strength to prevent fatigue of the respiratory muscle.

3. A method for determining a level of ventilatory assist as defined in claim 2, wherein calculating a critical signal strength of the electrical activity of the patient's respiratory muscle comprises:

calculating a critical value of a relative spectral change of the electrical activity of the patient's respiratory muscle above which long term fatigue of the respiratory muscle develops; and

using the critical value of the relative spectral change to calculate the critical signal strength of the electrical activity of the patient's respiratory muscle.

4. A method for determining a level of ventilatory assist as defined in claim 2, wherein calculating a critical signal strength of the electrical activity of the patient's respiratory muscle comprises:

determining a critical respiratory muscle force level above which muscle fatigue starts to develop; and

in response to the critical respiratory muscle force level, calculating a critical signal strength of the electrical activity of the patient's respiratory muscle under which isometric fatigue of the respiratory muscle does not develop.

5. A method for determining a level of ventilatory assist as defined in claim 1, wherein:

calculating a critical threshold of the respiration-related feature comprises calculating a critical level of a transdiaphragmatic pressure of the ventilator-dependent patient above which muscle fatigue develops; and

controlling the level of ventilatory assist comprises preventing the patient's transdiaphragmatic pressure to exceed the critical level of the transdiaphragmatic pressure to prevent fatigue of the respiratory muscle.

6. A method for determining a level of ventilatory assist as defined in claim 5, wherein calculating a critical level of the transdiaphragmatic pressure comprises:

calculating a critical value of a relative spectral change of the electrical activity of the patient's respiratory muscle above which long term fatigue of the respiratory muscle develops;

calculating a respiratory duty cycle; and

using the critical value of the relative spectral change and the respiratory duty cycle to calculate the critical level of the transdiaphragmatic pressure.

7. A method for determining a level of ventilatory assist as defined in claim 1, wherein calculating a critical threshold of the respiration-related feature comprises:

calculating a first critical signal strength of an electrical activity of the patient's respiratory muscle above which muscle fatigue develops; and

determining a critical muscle force level above which muscle fatigue develops and, in response to the critical muscle force level, calculating a second critical signal strength of the electrical activity of the respiratory muscle under which isometric fatigue of the respiratory muscle does not develop; and

wherein controlling the level of ventilatory assist comprises preventing the signal strength of the electrical activity of the respiratory muscle to exceed either the first and second critical signal strengths to prevent fatigue of the respiratory muscle.

8. A method for determining a level of ventilatory assist as defined in claim 1, wherein calculating a critical threshold of the respiration-related feature comprises:

calculating a critical level of a transdiaphragmatic pressure above which muscle fatigue develops; and

calculating a critical signal strength of an electrical activity of the patient's respiratory muscle above which muscle fatigue develops; and

wherein controlling the level of ventilatory assist comprises:

preventing the transdiaphragmatic pressure to exceed the critical level of the transdiaphragmatic pressure to prevent fatigue of the patient's respiratory muscle; and

preventing the signal strength of the electrical activity of the patient's respiratory muscle to exceed the critical signal strength to prevent fatigue of the patient's respiratory muscle.

9. A method for determining a level of ventilatory assist as defined in claim 1, wherein the patient's respiratory muscle comprises the patient's diaphragm.

10. A device for determining a level of ventilatory assist to a ventilator-dependent patient for reducing the risk of respiratory muscle fatique, the device comprising:

a calculator of a critical threshold of a respiration-related feature, wherein fatigue of a respiratory muscle of the ventilator-dependent patient develops when the critical threshold is reached by the respiration-related feature; and

a controller of the level of ventilatory assist to the ventilator-dependent patient in relation to the critical threshold of the respiration-related feature so as to prevent fatigue of the patient's respiratory muscle.

11. A device for determining a level of ventilatory assist as defined in claim 10, wherein:

the calculator computes a critical signal strength of an electrical activity of the patient's respiratory muscle above which muscle fatigue develops;

the device comprises a detector of the signal strength of the electrical activity of the respiratory muscle; and

the controller prevents the signal strength of the electrical activity of the patient's respiratory muscle to exceed the critical signal strength to prevent fatigue of the patient's respiratory muscle.

12. A device for determining a level of ventilatory assist as defined in claim 11, wherein the calculator:

calculates a critical value of a relative spectral change of the electrical activity of the patient's respiratory muscle above which long term fatigue of the respiratory muscle develops; and

uses the critical value of the relative spectral change to calculate the critical signal strength of the electrical activity of the patient's respiratory muscle.

13. A device for determining a level of ventilatory assist as defined in claim 11, wherein the calculator:

determines a critical respiratory muscle force level above which muscle fatigue starts to develop; and

in response to the critical respiratory muscle force level, calculates a critical signal strength of the electrical activity of the patient's respiratory muscle under which isometric fatigue of the respiratory muscle does not develop.

14. A device for determining a level of ventilatory assist as defined in claim 10, wherein:

the calculator computes a critical level of a transdiaphragmatic pressure of the ventilator-dependent patient above which muscle fatigue develops;

the device comprises a detector of the patient's transdiaphragmatic pressure; and

the controller prevents the patient's transdiaphragmatic pressure to exceed the critical level of the transdiaphragmatic pressure to prevent fatigue of the patient's respiratory muscle.

15. A device for determining a level of ventilatory assist as defined in claim 14, wherein the calculator:

calculates a critical value of a relative spectral change of the electrical activity of the patient's respiratory muscle above which long term fatigue of the patient's respiratory muscle develops;

calculates a respiratory duty cycle; and

uses the critical value of the relative spectral change and the respiratory duty cycle to calculate the critical level of the patient's transdiaphragmatic pressure.

16. A device for determining a level of ventilatory assist as defined in claim 10, wherein:

the calculator (a) calculates a first critical signal strength of an electrical activity of the patient's respiratory muscle above which muscle fatigue develops, and (b) determines a critical muscle force level above which muscle fatigue starts to develop and, in response to the critical muscle force level, calculates a second critical signal strength of the electrical activity of the patient's respiratory muscle under which isometric fatigue of the respiratory muscle does not develop;

the device comprises a detector of the signal strength of the electrical activity of the patient's respiratory muscle; and

the controller prevents the signal strength of the electrical activity of the patient's respiratory muscle to exceed either the first and second critical signal strengths to prevent fatigue of the patient's respiratory muscle.

17. A device for determining a level of ventilatory assist as defined in claim 10, wherein:

the calculator (a) calculates a critical level of a transdiaphragmatic pressure above which muscle fatigue develops, and (b) calculates a critical signal strength of an electrical activity of the patient's respiratory muscle above which muscle fatigue develops;

the device comprises a detector of the patient's transdiaphragmatic pressure, and a detector of the signal strength of the electrical activity of the patient's respiratory muscle; and

the controller (a) prevents the transdiaphragmatic pressure to exceed the critical level of the transdiaphragmatic pressure to prevent fatigue of the respiratory muscle, and prevents the signal strength of the electrical activity of the patient's respiratory muscle to exceed the critical signal strength to prevent fatigue of the patient's respiratory muscle.

18. A device for determining a level of ventilatory assist as defined in claim 10, wherein the patient's respiratory muscle comprises the patient's diaphragm.